

REMARKS

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claim 7 is canceled without prejudice or disclaimer.

Claims 1-6 are not amended and presented as a courtesy to the Examiner.

Claims 1-6 are pending.

II. Rejections under 35 U.S.C. § 102/103

Claims 1-6 were rejected under 35 U.S.C §102(a) as anticipated by, or in the alternative, under 35 U.S.C §103(a) as unpatentable over Brugger et al. (U.S. Patent No. 6,554,789, herein “Brugger”). The Examiner contends that the filtration fraction value (FF) is equivalent to the claimed blood purifying rate and that Brugger’s blood flow rate (BFR) is equivalent to the claimed blood flow rate. Applicants respectfully traverse the rejections based on Brugger.

Initially, Brugger defines his terms as follows: prescribed blood flow rate (BFR); replacement fluid flow rate (RFR); ultrafiltration volume flow rate (UFR); and filtration fraction value (FF). *See*, Brugger, column 20, lines 46-54.

Applicants submit that Brugger does not use a “formula based on parameters including a preset blood flow rate of said blood pump and a preset blood purifying rate of said blood purifier” as claimed in claim 1. Brugger clearly states that his invention “periodically compares the derived fluid reduction value, based upon hematocrit sensing by the sensors, with the desired FF.” Brugger,

column 24, lines 32-33. The FF is only pre-set or set by a physician¹ and is not based on the claimed factors.

Below is a detailed analysis of how one of ordinary skill in the art would have understood Brugger to have reached his conclusion above. In reviewing Brugger, Brugger is silent as to the exact position of the hemocrit sensor in the venous blood return path² other than it is downstream of the hemofilter 34. However, given Brugger's definition of post-treatment hematocrit (*see*, column 24, lines 21-27) one of ordinary skill in the art would know that the sensor must be upstream of the intersection of the replacement fluid line 70 to the venous blood return path 64.³ Given Brugger's disclosure to determine the position of the sensor, one of ordinary skill in the art would know the calculation for the balance of the pre-treatment hematocrit (pre-Ht) to the post-treatment hematocrit (postHt), which will equal:

$$\text{preHt} \times \text{BFR} = \text{postHt} \times (\text{BFR} - \text{UFR} - \text{RFR}) \quad (1)$$

Brugger also introduces the relationship of:

$$\text{BFR} = (\text{RFR} + \text{UFR}) / \text{FF} \quad (2)$$

Rearranging equation (2):

$$\text{BFR} \times \text{FF} = \text{RFR} + \text{UFR} \quad (3)$$

Substituting equation (3) into equation (1) and reducing:

$$\text{preHt} \times \text{BFR} = \text{postHt} \times (\text{BFR} - (\text{RFR} + \text{UFR}))$$

$$\text{preHt} \times \text{BFR} = \text{postHt} \times (\text{BFR} - (\text{BFR} \times \text{FF}))$$

$$\text{preHt} \times \text{BFR} = \text{postHt} \times (1 - \text{FF}) \times \text{BFR}$$

¹ *See*, Brugger, column 21, lines 44-45.

² *See*, Brugger, column 24, lines 14-20.

³ *See*, Brugger, Figure 11, upper left hand section of drawing.

preHt/postHt = 1-FF (4)

Thus, Brugger's blood concentration ratio is only based on the filtration fraction value (FF) and does not include other factors. Further, one of ordinary skill in the art would not go against both the explicit teaching of the reference and the mathematical solution behind the statement to attempt to use any other factors.

Claims 2-6 depend from claim 1 and are allowable based at least on the arguments above. Thus, Brugger does not disclose the claimed invention and Applicants request that the rejection be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number indicated below if the Examiner believes any issue can be resolved through either a Supplemental Response or an Examiner's Amendment.

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Respectfully submitted,

By


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